



DOSSIER · SUBSTANCE

Saw Palmetto (Serenoa Repens)

Saw palmetto is one of the longest and most broadly studied medicinal plants. Controlled human research focuses almost entirely on benign prostatic hyperplasia and lower urinary tract symptoms. Notably, the most frequently cited works in the entire field address not efficacy but interactions with medicinal products.

471

STUDIES IN
TOTAL

181

IN HUMANS

82

OF WHICH
CONTROLLED

37

IN ANIMALS

30

IN THE LAB

Figures from the IHR study database · Last updated 2026-10-15

How to Read This Dossier

ESTABLISHED

measured in humans, with a comparison group

PLAUSIBLE

supported by mechanism, animal studies or observation

HYPOTHESIS

a likely connection that still needs to be tested

Saw Palmetto (Serenoa repens) at a Glance

ORIGIN:
Saw palmetto (Serenoa repens) is the extract from the plant of the same name, described in the literature as the lipido-sterol extract of the dwarf palm. It is investigated as a phytotherapeutic agent for benign prostatic hyperplasia and the associated lower urinary tract symptoms. A single defined lead substance is not described; extraction methods alter the pharmacological profile of the extracts.

EVIDENCE BASE:
471 evaluated studies · 82 controlled human studies · 99 observational studies · 16 review articles · 37 animal studies · 29 cell culture studies

- STRONGEST EVIDENCE:**
- Efficacy: The 1998 review article pools 18 randomised controlled trials with 2939 men with symptomatic BPH, for a mean of 9 weeks, of which 16 were double-blind.
 - Further investigations: The 2004 meta-analysis evaluates 14 randomised and three open studies in 4280 patients: IPSS reduction 4.78 (0.41), maximum urinary flow rate additionally plus 1.02 (0.50) ml/s (P = 0.042).
 - Further investigations: The 2000 meta-analysis over 11 randomised and two open studies in 2859 patients estimates an additional increase in maximum urinary flow rate of 2.20 ± 0.51 ml/s (P < 0.001).
 - Further investigations: In 85 men the symptom score fell from 16.7 to 12.3 versus 15.8 to 13.6 under placebo (P = 0.038); the maximum urinary flow rate did not differ (P = 0.73).
 - Further investigations: After 12 months the I-PSS fell by 4.4 points in both groups; the increase in maximum urinary flow rate was similar (1.8 versus 1.9 ml/s); ejaculatory disorders occurred.

- LIMITATIONS:**
- The 2006 double-blind study in 225 men found no significant group difference over one year: the mean difference in AUASI change was 0.04 points (95 % CI -0.93 to 1.01).
 - The studies themselves name the heterogeneity of the extracts and their inconsistent characterisation in the trials; anyone comparing results may be comparing different extracts.
 - It remains open which concrete interaction data on saw palmetto are available; the most frequently cited works in the field address interactions with medicinal products, in the extract without specific data.

CLASSIFICATION:
Saw palmetto is a widely studied plant extract in benign prostatic hyperplasia whose findings apply only in conjunction with the underlying extract profile.

1. What Saw Palmetto Is

Saw palmetto is the extract from the plant of the same name. The studies work with differently prepared extracts; a hexanic extract carries its own preparation name (Permixon) in several works. Saw palmetto extracts also appear in studies on drug interactions and on the characterisation of herbal preparations. The literature describes the substance via its extracts and their production, not via a single defined lead substance. This is the difference from a chemically uniform medicinal substance.

Decisive for the understanding of all studies is that saw palmetto is not a uniform substance. Extraction methods alter the pharmacological profile of the extracts, as a dedicated review article records. A further study examines how inadequately herbal preparations are characterised in randomised controlled trials. Anyone comparing results may therefore be comparing different extracts. Added to this is absorption: saw palmetto extracts appear in studies on the influence of metabolic enzymes and transporters as well as in an investigation of cytochrome P450 phenotypes in humans. Extract composition and interaction potential are therefore two levels that every classification must carry.

2. What the Studies Show in Detail

The supporting human studies and the most important reviews — by indication, with population, duration, preparation, measured variable and result, as the original studies report them. Numbers appear only where the study names them.

Distribution of the **controlled human studies** by indication — the numbers are not additive, as one study may be assigned to several areas:

INDICATION	CONTROLLED STUDIES
Safety and tolerability	38
Metabolism	13
Oncology	6
Inflammatory processes	5
Fatigue and stress	5
Oxidative stress	3

INDICATION	CONTROLLED STUDIES
Musculoskeletal system	3
Immune system	3

Safety and Tolerability

The 1998 systematic review included 18 randomised controlled trials with 2939 men with symptomatic benign prostatic hyperplasia (BPH); the mean study duration was 9 weeks (range 4 to 48 weeks), 16 studies were double-blind, and in 9 the concealment of treatment allocation was adequate ¹. Many studies did not report their results in a form that permitted meta-analysis ¹. The 2006 double-blind study randomised 225 men over 49 years with moderate to severe BPH symptoms to one year of treatment with saw palmetto extract (160 mg twice daily) or placebo ². Primary endpoints were the change in the American Urological Association Symptom Index (AUASI) and the maximum urinary flow rate ². No significant group difference was found: mean difference in AUASI change 0.04 points (95 % confidence interval -0.93 to 1.01), in maximum urinary flow rate 0.43 ml per minute (95 % CI -0.52 to 1.38); prostate size, residual urine volume, quality of life and serum PSA also did not differ, and the adverse-event rate was similar in both groups ².

The open, randomised one-year study from 2004 examined 64 men aged 24 to 58 years (mean age 43.2) with chronic pelvic pain syndrome (CP/CPPS) who were randomised to finasteride (5 mg once daily) or saw palmetto (325 mg daily) ¹². All 64 men had previously received antibiotics (duration 3 to 93 weeks), 52 (82 %) had been on alpha-blockers; 61, 57 and 56 patients were evaluable after 3, 6 and 12 months ¹². After one year the mean NIH-CPSI score fell in the finasteride group from 23.9 to 18.1 ($p < 0.003$), in the saw palmetto group from 24.7 to 24.6 ($p = 0.41$) ¹². The 2000 review article classifies that saw palmetto is safe in BPH and has no recognised adverse effects, that serum PSA remains unaffected and that the clinical relevance of the mechanisms shown in vitro is largely unavailable ¹⁸.

The 2015 review on phytotherapy for BPH names saw palmetto alongside *Pygeum africanum* and *Urtica dioica* as medicinal plants frequently used for mild to moderate symptoms ⁹. Preclinically derived mechanisms of action mentioned include 5-alpha-reductase inhibition, alpha-adrenergic antagonism as well as inhibition of dihydrotestosterone and oestrogen receptors ⁹. Randomised clinical trials show significant efficacy for some phytotherapeutics in improving urinary tract symptoms and mild side effects, while for others (e.g. *Epilobium* spp., *Secale cereale*, *Roystonea regia*) further clinical evidence is required ⁹.

Regarding interactions with medicinal products, the updated systematic review of 2009 recorded 128 case reports or case series and 80 clinical studies on seven common medicinal plants, including saw palmetto ³¹. The interactions reported in detail in the extract concern St John's wort via CYP and P-glycoprotein induction as well as Ginkgo; for saw palmetto the present extract names no specific interaction data ³¹. The 2012 review classifies saw palmetto among the medicinal plants that appear to carry a low risk under conventional pharmacotherapy, whereas individual plants, notably St John's wort, can trigger sufficiently serious events to endanger health ³². It remains open which concrete interaction data for saw palmetto are available from case reports and controlled studies.

Metabolism

After a four-week run-in phase, 704 patients were randomised to tamsulosin 0.4 mg/day (N = 354) or Permixon 320 mg/day (N = 350); endpoint analysis was performed on the per-protocol population of 542 patients (tamsulosin: N = 273; Permixon: N = 269) ³. After 12 months the I-PSS fell by 4.4 in both groups, with no differences in irritative or obstructive symptom improvement; the rise in Qmax was similar (1.8 ml/s Permixon, 1.9 ml/s tamsulosin) ³. PSA remained stable, prostate volume decreased slightly in the Permixon-treated patients; both substances were well tolerated, yet ejaculatory disorders occurred ³.

The 2004 phenotypic study examined in 12 healthy volunteers (6 women, 6 men) whether 28-day supplementation with *Citrus aurantium*, *Echinacea purpurea*, milk thistle or saw palmetto alters the activity of CYP1A2, CYP2D6, CYP2E1 or CYP3A4 ³³. A 30-day wash-out phase separated each supplementation period; probes were midazolam and caffeine, followed 24 hours later by chlorzoxazone and debrisoquine, and phenotype measurements were obtained via serum ratios of 1-hydroxymidazolam/midazolam (1-hour sample), paraxanthine/caffeine (6-hour sample), 6-hydroxychlorzoxazone/chlorzoxazone (2-hour sample) and urinary recovery of debrisoquine (8-hour collection) ³³. The comparison of measurements before and after supplementation is truncated in the present extract; the content of the presumed active phytochemicals was determined for each supplement ³³.

The 2000 review article describes that phytotherapeutic preparations have been prescribed in Europe for more than 20 years for the treatment of symptomatic BPH and in these countries account for approximately one third of the total sales of all therapeutics sold for BPH treatment; in France they are the most widely used medicines for BPH treatment ⁴⁰. The work addresses several phytotherapeutics and names among them *Serenoa repens* (Permixon), a lipido-sterolic extract of the dwarf palm that, as a registered medicinal product of Pierre Fabre Medicament, is subject to strict quality control for stability of constituent composition ⁴⁰. It remains to be clarified how the measured enzyme activities under saw palmetto behave in larger samples and in patients on multiple medication.

Exhaustion and Stress

The double-blind, multicentre, placebo-controlled randomised study of 2011 was conducted at 11 North American centres between 5 June 2008 and 10 October 2010 and enrolled 369 men aged 45 years and older, with a maximum urinary flow rate of at least 4 ml/s and an AUASI score between 8 and 24 at two screening visits ⁴. One, two and then three doses (320 mg/day) of saw palmetto extract or placebo were administered, with dose escalations after 24 and 48 weeks ⁴. The primary endpoint was the difference in AUASI score between baseline and 72 weeks; secondary endpoints included urinary urgency, nocturia, maximum uroflow rate, post-void residual volume, PSA value, global participant assessments as well as indices for sexual function, continence, sleep quality and prostatitis symptoms ⁴. The result values of the abstract are truncated in the present extract; it is reported that the mean AUASI scores changed between baseline and 72 weeks ⁴.

The 2009 systematic review on adverse events of saw palmetto searched five electronic databases from their inception to February 2008, checked reference lists and departmental files and requested information from spontaneous reporting systems of the WHO and national safety authorities ¹⁴. Twenty-four manufacturers or distributors of saw palmetto preparations and four medicinal plant organisations were contacted; there were no language restrictions,

and only reports of adverse events in humans after monoprparations of saw palmetto were included ¹⁴. Forty articles were included, among them 26 randomised controlled trials, 4 non-randomised controlled trials and 6 uncontrolled studies ¹⁴. It remains open which adverse events were shown in detail for monoprparations in this evaluation and how they compare with placebo.

Further Investigations

The updated 2004 meta-analysis evaluated 14 randomised clinical trials and three open studies on Permixon with a total of 4280 patients; the studies comprised 22 to 1100 patients and lasted 21 to 720 days ⁵. The most frequent endpoints were maximum urinary flow rate and nocturia; statistical evaluation was performed as a random-effects meta-analysis ⁵. Permixon was associated with a mean (SEM) reduction in the International Prostate Symptom Score of 4.78 (0.41); the mean placebo effect on maximum urinary flow rate was an increase of 1.20 (0.49) ml/s, the estimated effect of Permixon an additional increase of 1.02 (0.50) ml/s ($P = 0.042$) ⁵. Placebo was associated with a reduction in the mean number of nocturnal voids of 0.63 (0.14), with an additional reduction attributable to Permixon of 0.38 (0.07) ($P < 0.001$); for nocturia there was some heterogeneity between the studies ⁵.

The earlier 2000 meta-analysis was based on 11 randomised clinical trials and 2 open studies on Permixon with 2859 patients; the studies ranged from 22 to 592 patients and lasted 21 to 180 days ⁶. The mean ($\pm$ SE) placebo effect on maximum urinary flow rate was an increase of 0.51 ± 0.51 ml/s, the estimated effect of Permixon an additional increase of 2.20 ± 0.51 ml/s ($P < 0.001$) ⁶. Placebo was associated with a reduction in the mean number of nocturnal voids of 0.69 ± 0.15 , with an additional reduction of 0.50 ± 0.01 voids ($P < 0.001$) attributed to Permixon; there was some heterogeneity between the studies, and treatment duration appeared to have no influence on either effect ⁶.

The randomised, double-blind, placebo-controlled study of 2001 enrolled 85 men aged 45 years and older with an International Prostate Symptom Score of at least 8 who, after a one-month placebo run-in phase, received saw palmetto or placebo for six months ⁷. The International Prostate Symptom Score, a sexual function questionnaire and urinary flow rate were assessed ⁷. The mean symptom score fell in the saw palmetto group from 16.7 to 12.3 versus 15.8 to 13.6 under placebo ($P = 0.038$); the quality-of-life score improved more strongly in the saw palmetto group, without statistical significance, and the sexual function questionnaire showed no change in either group ⁷. Maximum flow rate rose by 1.0 ml/s and 1.4 ml/s in the saw palmetto and placebo groups respectively ($P = 0.73$) ⁷.

The 2012 review article examined randomised studies in which men with symptomatic BPH received preparations of *Serenoa repens* (alone or in combination) for at least four weeks against placebo or other interventions and clinical endpoints were recorded ¹⁰. The 2009 study investigated in a randomised, double-blind, placebo-controlled design over 12 months 47 BPH patients with a mean age of 53.3 years and an International Prostate Symptom Score above 8 who received sweet potato starch (group A, placebo, 320 mg/day), pumpkin seed oil (group B, 320 mg/day), saw palmetto oil (group C, 320 mg/day) or pumpkin seed oil plus saw palmetto oil (group D, 320 mg/day each) ¹⁵. In groups B, C and D the symptom score was reduced after 3 months; the quality-of-life score improved in group D after 6 months, in groups B and C after 3 months; serum PSA was reduced only in group D after 3 months, and prostate volume did not differ in any group ¹⁵. Maximum urinary flow rate improved stepwise in groups B and C, with statistical significance after 6 months in group B and after 12 months in group C ¹⁵. Because group D received a combination of pumpkin seed oil and saw palmetto oil, the effect observed there cannot be attributed to the single substance saw palmetto.

The 1998 study treated 50 men with previously untreated urinary tract symptoms and an International Prostate Symptom Score of at least 10 for six months with a commercially available saw palmetto preparation (160 mg twice daily) ¹⁷. Maximum urinary flow rate, post-void residual volume, pressure-flow study and serum PSA were recorded at baseline as well as symptom score and PSA every two months, with repeat urodynamics after six months ¹⁷. The mean IPSS improved in the 46 men who completed the study from 19.5 ± 5.5 to 12.5 ± 7.0 ($P < 0.001$), with a significant improvement already evident after two months; an improvement in symptom score of 50 % or more was found in 21 % (10 of 48), 30 % (14 of 47) and 46 % (21 of 46) of patients after 2, 4 and 6 months ¹⁷. Maximum urinary flow rate, post-void residual volume and detrusor pressure at maximum flow did not change significantly in the patients completing the study ¹⁷.

The 2014 review article on extraction technique emphasises that the qualitative and quantitative composition of the bioactives depends on the extraction procedure and products of the same plant may therefore differ in their clinical efficacy, without interchangeability between different commercial brands ³⁹. The 2005 study examined all English-language randomised controlled trials on single-plant preparations of Echinacea, garlic, Ginkgo, saw palmetto or St John's wort listed in MEDLINE between 1 January 2000 and 9 February 2004 ¹³. Of 81 included studies, 12 (15 %) reported tests for quantification of the actual ingredients, and 3 (4 %) provided sufficient data to compare actual with expected content values of at least one chemical constituent; in these 3 studies the actual content varied between 80 % and 113 % of the expected values ¹³. It remains to be clarified how the effects on symptom score and nocturia shown in the meta-analyses of 2000 and 2004 can be reconciled with the null findings of the large randomised studies of 2006 and 2011.

Intestine and Microbiome

The 2018 systematic review and meta-analysis evaluated the efficacy and safety of the hexanic extract of *Serenoa repens* (HESr, Permixon) at a dose of 320 mg daily as monotherapy in urinary tract symptoms associated with benign prostatic hyperplasia ⁸. Included were randomised controlled trials and prospective observational studies identified up to March 2017 via Medline, Web of Knowledge, Scopus, the Cochrane Library and bibliographic references; works on other saw palmetto extracts than Permixon were excluded ⁸. International Prostate Symptom Score, maximum urinary flow rate, nocturia, quality of life, prostate volume, sexual function and adverse drug reactions were recorded; data from randomised and observational studies were analysed jointly and separately with a random-effects model, supplemented by a subgroup analysis of treatments lasting at least one year ⁸. Compared with placebo, HESr was associated with 0.64; the corresponding 95 % confidence interval is truncated in the present extract ⁸.

The 2010 review article classifies saw palmetto among the best-selling herbal medicinal products whose possible effects on the enzymes and transporters involved in gastrointestinal drug absorption it evaluates ³⁶. It is based on in-vivo and in-vitro experiments as well as clinical studies; the work emphasises that knowledge of the mechanisms of plant-drug interactions is essential for clinical risk assessment ³⁶. The 2011 review article summarises for nine botanicals, including saw palmetto, the effects on metabolic enzymes and transporters that influence absorption and distribution of herbal products, separating the origin of the samples (extracts and individual components), the species (human and animal) as well as in-vivo and in-vitro systems ³⁷. It remains open which concrete absorption and transporter effects for saw palmetto were measured in controlled human studies.

Inflammatory Processes

The double-blind pilot study of 2003 was conducted multicentre with two parallel groups in BPH patients who were randomised to receive either oral Permixon 160 mg twice daily for three months or to be observed without treatment for three weeks before surgery (control group) ¹¹. Strict inclusion and exclusion criteria were intended to ensure homogeneous groups and avoid interference by anti-inflammatory or other medications ¹¹. The baseline clinical profile was nearly identical in both groups: age 65.7 ± 5.1 versus 67.1 ± 5.8 years, IPSS 19.8 ± 6.1 versus 19.0 ± 5.8 , prostate volume 64.8 ± 18.9 versus 71.5 ± 29.3 cc, Qmax 9.6 ± 3.2 versus 10.6 ± 2.6 ml/s and QL 4.0 ± 1.1 versus 3.5 ± 0.7 ¹¹. In 29 patients (17 controls, 12 Permixon) surgery was ultimately performed by transurethral prostate resection or retropubic adenomectomy; the adenoma samples were stained with HE and prepared for immunohistochemical examinations ¹¹. The result values of the abstract are truncated in the present extract.

The 2004 review article screened more than 30 publications via MEDLINE on laboratory studies with saw palmetto extracts that investigated the question of a mechanism of action ³⁸. The n-hexane lipido-sterolic extract of *Serenoa repens*, Permixon, is accordingly the product that, like no other of such preparations, has been scientifically investigated ³⁸. Placebo-controlled and comparative clinical studies on Permixon point to efficacy in BPH and urinary tract symptoms; numerous mechanisms are discussed ³⁸.

The 2020 review article screened the literature in PubMed up to July 2019 on the role of a persistent prostatic inflammatory status (PIS) in the development and progression of BPH with urinary tract symptoms and on which approved drug therapies can reduce this status. The cause of the histologically defined persistent PIS is multifactorial; it is found in many men with LUTS/BPH, especially in older men and in those with large prostate volume or more severe storage symptoms, and is associated with increased risk of acute urinary retention and symptom worsening. Of the approved therapies, the current evidence for reduction of persistent PIS is greatest for the hexanic extract of *Serenoa repens*; this treatment alleviates the symptoms to the same extent as α 1-adrenoceptor antagonists and short-term 5 α -reductase inhibitors, while only limited evidence is available for other standard therapies. It remains to be clarified which histological and molecular inflammatory markers change under saw palmetto in controlled studies with adequate case numbers.

Oncology

The open multicentre pilot study of 2005 investigated in two parallel groups of BPH patients the effect of Permixon on molecular mechanisms of apoptosis, namely the ratio of Bax to Bcl-2 expression and caspase-3 activity in prostate tissue ¹⁶. The patients were randomised either to be observed without treatment for three weeks before surgery (control group) or to receive 160 mg *Serenoa repens* twice daily orally for three months before the same operation ¹⁶. In 17 controls and 12 patients surgery was ultimately performed, by transurethral prostate resection or retropubic adenomectomy; Bax and Bcl-2 expression as well as caspase-3 activity were determined by Western blot in 15 controls and 10 patients and reported blinded ¹⁶. The Bax-to-Bcl-2 ratio, which serves as an apoptosis index, was significantly elevated in the prostate tissue of the treated patients; the proportion of the intact 116-kDa form of poly(ADP-ribose) polymerase, an enzyme involved in apoptotic cell death, was reduced in the tissue of the patients treated with *Serenoa repens*, indicating increased caspase-3 activity in the prostate ¹⁶.

The 1999 review classifies saw palmetto among the potentially safe medicinal plants, alongside feverfew, garlic, ginkgo, Asian ginseng, St John's wort and valerian ³⁴. Clinical studies were used, among other things, to evaluate saw palmetto in benign prostatic hyperplasia; on the basis of clinical studies, case reports and further scientific literature the German Commission E established indications and dosage recommendations for many herbal therapies ³⁴. The tissue findings reported here derive from molecular analysis of surgical specimens from a small number of cases; it remains open whether these apoptosis markers can be reproduced in larger controlled studies and whether they correlate with clinical courses.

Heart and Circulation

The 2001 systematic review searched Medline, the Cochrane Library, Embase and Phytobase from their inception to July 2000 for data on interactions between medicinal plants and prescribed medicines ³⁰. All data on plant-drug interactions were included, irrespective of whether they were based on case reports, case series, clinical studies or other human investigations; in-vitro experiments were excluded ³⁰. Forty-one case reports or case series and 17 clinical studies on the seven best-selling medicinal plants ginkgo, St John's wort, ginseng, garlic, echinacea, saw palmetto and kava were identified ³⁰. The reported results concern, in detail, St John's wort, which lowers blood concentrations of ciclosporin, amitriptyline, digoxin, indinavir, warfarin, phenprocoumon and theophylline and, when given concomitantly with contraceptives, loperamide or selective serotonin-reuptake inhibitors, triggers intermenstrual bleeding, delirium or a mild serotonin syndrome, as well as ginkgo, whose interactions include bleeding when combined with warfarin and raised blood pressure ³⁰.

For saw palmetto the present extract of this review cites no specific interaction data; the plant is listed as one of the seven medicinal plants examined ³⁰. This leaves open the question of which concrete cardiovascular interactions for saw palmetto are documented in case reports and controlled studies and whether they become clinically relevant with drugs that have a narrow therapeutic index.

Oxidative Stress

The 2000 review on medicinal plants and human physical performance lists saw-palmetto berries among the plants currently used to enhance physical performance, irrespective of scientific evidence for an effect ³⁵. The same list includes Chinese, Korean and American ginseng, Siberian ginseng, ma huang or Chinese ephedra, ashwagandha, rhodiola, yohimbe, cordyceps, shilajit, smilax, oats, muira puama, suma, Tribulus terrestris, beta-sitosterol and related sterols, and wild yam ³⁵. The review therefore covers many agents, not only saw palmetto. Controlled studies on Asian ginsengs showed improvements in physical performance when most of the following conditions were met: use of standardised root extracts, study duration longer than 8 weeks, daily dose above 1 g dried root or equivalent, large participant number and older participants ³⁵. Improvements in muscle strength, maximal oxygen uptake, work capacity, fuel homeostasis, serum lactate, heart rate, visual and auditory reaction times, alertness and psychomotor abilities were repeatedly documented; Siberian ginseng yielded mixed results, ma huang, ephedrine and related alkaloids improved physical performance only when combined with caffeine, and other plants remained practically untested ³⁵.

For saw palmetto the review therefore reports a use for performance enhancement without scientific evidence of an effect; the work itself presents no controlled findings on saw palmetto ³⁵. It remains open whether an ergogenic or oxidative effect of saw palmetto can be examined at all in controlled studies and which endpoints would be suitable for that purpose.

Overall Picture

Across the domains two groups of findings stand out: the meta-analyses of 2000 and 2004, which in 2859 and 4280 patients respectively showed a reduction in symptom score and nocturia as well as an increase in maximum urinary flow rate versus placebo^{6 5}, and the large randomised studies of 2006 and 2011, which in 225 and 369 men at a dose of 160 mg twice daily for one year or up to 320 mg daily for 72 weeks found no significant differences from placebo in AUASI, maximum urinary flow rate, prostate size, residual urine volume, quality of life or PSA^{2 4}. The 2014 review attributes the differing clinical efficacy of products from the same plant to the extraction procedure and denies interchangeability between commercial brands³⁹; the 2005 study found that only 3 of 81 randomised studies supplied sufficient data to compare actual with expected ingredient contents, with variations between 80 % and 113 %¹³.

In the area of safety several reviews classify saw palmetto as having few side-effects: the 2000 work names no recognised side-effects and no influence on serum PSA¹⁸, the 2012 review counts saw palmetto among the plants with low risk under conventional pharmacotherapy³², and the 1999 review lists it among the potentially safe medicinal plants³⁴. The systematic evaluation of adverse events from 2009 was based on 40 articles, including 26 randomised controlled trials¹⁴. For the specific interaction data on saw palmetto the interaction reviews of 2001 and 2009 cite no individual findings in the present extract, whereas the 2012 review assumes a low risk^{30 31 32}. The tissue studies on apoptosis and inflammation work with surgical specimens from small case numbers and must be read as preclinical-molecular findings; an effect in humans has therefore not been examined^{16 11}; the 2020 review sees the strongest evidence for a reduction in persistent prostatic inflammatory status with the hexane extract. Open questions concern the standardisation of the extracts, the transferability of the meta-analysis effects to the large randomised studies and the interaction data for saw palmetto itself.

Methodology of the evidence base

The material comprises randomised, double-blind and placebo-controlled studies, open randomised comparisons, prospective observational studies, meta-analyses and narrative reviews. Treatment duration ranges from 21 days to 720 days, in the large randomised studies up to 72 weeks^{5 4}. Frequent endpoints are the International Prostate Symptom Score or the American Urological Association Symptom Index, maximum urinary flow rate, nocturia, residual urine volume, prostate volume, serum PSA, quality of life and sexual function; safety endpoints and adverse drug reactions are also included^{2 8 5}. Systematic characterisation of the preparations used is lacking: in a review of herbal agents overall only 3 of 81 randomised studies supplied sufficient data to compare actual with expected ingredient contents¹³, and composition depends on the extraction procedure³⁹. Likewise missing are results reported in meta-analysable form¹ and specific interaction data for saw palmetto in the interaction reviews^{30 31}.

Saw palmetto is not a uniform active substance

The thesis states that extract diversity is the real open question in the field. A 2014 paper shows how modern extraction procedures alter the pharmacological profile of saw-palmetto extracts. Another from 2005 notes that herbal preparations in published randomised studies are frequently inadequately characterised. Taken together this means: two studies using the same plant name may have tested different extracts.

PLAUSIBLE:

Part of the inconsistent findings is explained by this, not by the plant itself.

A second point concerns weighting. The most-cited works in the entire field are reviews on interactions between herbal and prescription medicines as well as an investigation into the influence on cytochrome-P450 phenotypes in humans. This does not mean that saw palmetto has clinically relevant interactions; it means that the most influential literature in the field poses this question.

HYPOTHESIS:

Attention follows the safety question, not the efficacy question.

3. How Robust the Research Is

The research is distributed unevenly. The largest block consists of observational studies in humans, followed by controlled studies in humans and then by basic-research-oriented work. Within the controlled studies in humans a single domain dominates: safety. All other application areas — metabolism, oncology, inflammation, exhaustion, antioxidant questions, musculoskeletal system, immune system, gut and cardiovascular — are each represented by only a few papers. In content the field revolves around benign prostatic hyperplasia and lower urinary-tract symptoms; the most-cited controlled studies almost without exception address this indication, sometimes in comparison with an alpha-blocker or with finasteride.

Methodologically the field is mature: several meta-analyses and systematic reviews exist, reaching back to the 1990s, including a 2012 review. This is offset by a weakness the works themselves name: the heterogeneity of the extracts and their incomplete characterisation in the studies. The most-cited works in the entire field moreover do not address efficacy but interactions of herbal agents with medicines. What must be clarified next is therefore clearly outlined: whether the results can be reproduced across defined extract profiles.

4. What Is Frequently Claimed — and What the Data Support

STATEMENT	EVIDENCE BASE
Saw palmetto is effective in benign prostatic hyperplasia	The question has been examined multiple times since 1998 in meta-analyses and large randomised studies; the works extend to 2018. The titles name the research
Saw palmetto is comparable to alpha-blockers or finasteride	Direct comparisons are available, including with an alpha-blocker and with finasteride. Whether equivalence exists cannot be inferred from the titles available.
Saw palmetto is well tolerated	Safety is the largest single area of controlled human studies; a systematic review on adverse events dates from 2009.
Saw palmetto can be combined with medicines without risk	Interactions are a focus of the most cited literature in the field, from reviews to a study on metabolic enzymes in humans.

5. Profile: Molecule and Charge

Saw palmetto (Serenoa repens) is not a single molecule, but a **mixture** — there is no molecular formula and no fixed molecular mass. What can be described are functional groups, charge behaviour and redox properties; that is exactly what the next section is about.

6. Charge, Electrons, Radicals

This is a measurement on a dispersion, not a statement about cation exchange. Both findings come from cell culture and cell-free assay.

A measurement of electron transfer or the redox behaviour of the saw palmetto molecule itself is still outstanding in the evidence statements. In patent compositions, redox-active accompanying substances such as ubidecarenone (coenzyme Q10), idebenone and decylubiquinone appear ^{25 25}; these are combinations from which no effect of the individual substance can be derived. In hair care products, saw palmetto extract is listed alongside superoxide dismutase and other additives as one of at least ten constituents ^{26 27}. In these statements, no electrochemical quantity has been measured in humans. What would need to be clarified is whether charge, radical scavenging activity and redox behaviour can be captured in a controlled human design.

7. Interactions with Other Substances

With which other substances of the platform this substance is **jointly** investigated or discussed in human studies and review articles — combination, comparison or common mechanism of action. The number names works in which both occur.

SUBSTANCE	JOINT WORKS	OF WHICH CONTROLLED IN HUMANS
Adaptogens	19	2
Chronic inflammation	19	5
Ginkgo biloba	17	2
Art therapy	17	9
Garlic and black garlic	13	1
Selenium	11	4
Green tea and EGCG	10	3
Turmeric and curcumin	5	2

SUBSTANCE	JOINT WORKS	OF WHICH CONTROLLED IN HUMANS
Stress, cortisol and inflammation	5	3
Milk thistle (silymarin)	5	0

Several mechanisms of action have been postulated for saw palmetto (*Serenoa repens*) on the basis of preclinical work: inhibition of 5 α -reductase, alpha-adrenergic antagonism and inhibition of dihydrotestosterone and oestrogen receptors. A review found no evidence for interactions with medicinal products: there were no indications of interactions of *S. repens* ¹⁴; saw palmetto extract shows no interactions and no serious adverse events in blood biochemical parameters when administered concomitantly with other medicinal products, even with long-term use ²³. A specific systematic review on interactions and adverse events was lacking at that time ¹⁴.

Combinations were investigated. In a controlled study, patients received a fixed combination of saw palmetto fruit and nettle root extract (PRO 160/120) or finasteride ²⁸. A combination of cernitin, saw palmetto, beta-sitosterol and vitamin E reduced nocturia and micturition frequency over 3 months compared with placebo and caused no substantial adverse effects ^{29,29}. It remains to be examined whether saw palmetto alters CYP enzymes or the uptake of concomitantly administered substances.

8. Overdosage, Tolerability, Limits

In controlled human studies, adverse effects of saw palmetto were described as mild and rare; erectile dysfunction occurred more frequently under finasteride at 4.9 % than under saw palmetto at 1.1 % ($P < .001$) ¹. Dose escalation of a saw palmetto fruit extract led to no clearly attributable adverse effects ⁴. In a meta-analysis the safety profile was favourable, with gastrointestinal complaints being the most frequent adverse drug reaction (mean incidence 3.8 %) ⁸.

The available evidence makes no statements on upper limits or contraindications; what would need to be clarified is whether dose–response relationships for adverse effects exist with longer-term use.

9. The Most Robust Works

Ordered by strength of evidence, not by familiarity. The complete evaluation comprises considerably more works; the most robust ones are listed here.

Controlled Human Studies

- ¹ Saw palmetto extracts for treatment of benign prostatic hyperplasia: a systematic review (1998)
- ² Saw palmetto for benign prostatic hyperplasia (2006)
- ³ Comparison of a phytotherapeutic agent (Permixon) with an alpha-blocker (Tamsulosin) in the treatment of benign prostatic hyperplasia: a 1-year ... (2002)
- ⁴ Effect of increasing doses of saw palmetto extract on lower urinary tract symptoms: a randomized trial (2011)
- ⁵ Updated meta-analysis of clinical trials of *Serenoa repens* extract in the treatment of symptomatic benign prostatic hyperplasia (2004)
- ⁶ Meta-analysis of clinical trials of permixon in the treatment of symptomatic benign prostatic hyperplasia (2000)
- ⁷ Randomized, double-blind, placebo-controlled trial of saw palmetto in men with lower urinary tract symptoms (2001)
- ⁸ Efficacy and safety of a hexanic extract of *Serenoa repens* (Permixon®) for the treatment of lower urinary tract symptoms associated with benign ... (2018)
- ⁹ What do we know about phytotherapy of benign prostatic hyperplasia? (2015)
- ¹⁰ *Serenoa repens* for benign prostatic hyperplasia (2012)
- ¹¹ BPH and inflammation: pharmacological effects of Permixon on histological and molecular inflammatory markers. Results of a double blind pilot ... (2003)
- ¹² A prospective, 1-year trial using saw palmetto versus finasteride in the treatment of category III prostatitis/chronic pelvic pain syndrome (2004)
- ¹³ Lack of herbal supplement characterization in published randomized controlled trials (2005)
- ¹⁴ *Serenoa repens* (saw palmetto): a systematic review of adverse events (2009)
- ¹⁵ Effects of pumpkin seed oil and saw palmetto oil in Korean men with symptomatic benign prostatic hyperplasia (2009)
- ¹⁶ *Serenoa repens* treatment modifies bax/bcl-2 index expression and caspase-3 activity in prostatic tissue from patients with benign prostatic ... (2005)
- ¹⁷ Saw palmetto (*Serenoa repens*) in men with lower urinary tract symptoms: effects on urodynamic parameters and voiding symptoms (1998)
- ¹⁸ Saw palmetto for the treatment of men with lower urinary tract symptoms (2000)
- ¹⁹ Tissue effects of saw palmetto and finasteride: use of biopsy cores for in situ quantification of prostatic androgens (2001)
- ²⁰ Evaluation of male sexual function in patients with Lower Urinary Tract Symptoms (LUTS) associated with Benign Prostatic Hyperplasia (BPH) treated ... (2005)
- ²¹ *Serenoa repens* extract for benign prostate hyperplasia: a randomized controlled trial (2003)
- ²² Evaluation of the clinical benefit of permixon and tamsulosin in severe BPH patients-PERMA study subset analysis (2004)

- ²³ Pharmacological effects of saw palmetto extract in the lower urinary tract (2009)
- ²⁴ Serenoa repens for benign prostatic hyperplasia (2009)

10. Summary

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Two meta-analyses are available for saw palmetto extracts in benign prostatic hyperplasia. The 2004 evaluation of 14 randomised and three open studies on a hexanic extract in 4280 patients estimates the reduction in symptom score at 4.78 (0.41) and the additional effect on maximum urinary flow rate at 1.02 (0.50) ml/s ($P = 0.042$); the 2000 evaluation of 11 randomised and two open studies in 2859 patients yields an additional increase of 2.20 ± 0.51 ml/s ($P < 0.001$) and an additional reduction in nocturnal voids of 0.50 ± 0.01 ($P < 0.001$). The 1998 review pools 18 randomised controlled trials with 2939 men and provides an indication of an effect.

Plausible is the connection between extract composition and effect profile: a hexanic extract is defined across several studies, other trials work with differently prepared extracts, and the studies themselves note their heterogeneity and inconsistent characterisation. As mechanisms derived from preclinical work, the 2015 review names 5-alpha-reductase inhibition, alpha-adrenergic antagonism and inhibition of dihydrotestosterone and oestrogen receptors; according to the 2000 review, the clinical relevance of the mechanisms shown in vitro is largely unavailable. **Hypothesis:** If the effects can be attributed to defined extract profiles, the lack of group difference in the double-blind one-year study from 2006 would rather be a question of the preparation than of the plant.

A study would need to clarify whether the results can be reproduced across defined extract profiles. For this, the extract composition would have to be fully characterised, maintained throughout the entire study period and, in addition to symptom score, maximum urinary flow rate and post-void residual volume, drug interactions would also have to be recorded. It also remains open which adverse events monopreparations show in detail and how they compare with placebo, and whether the measured cytochrome P450 activities can be confirmed in larger samples and in patients on multiple medications. A study that directly compares defined extracts against each other would answer the question of whether heterogeneity explains the results.

11. What Remains Open

- **Extracts:** Which extraction methods and which extract composition explain the inconsistent findings.
- **Interactions:** Which drug interactions are clinically relevant and via which enzymes they occur.
- **Comparison:** Whether saw palmetto holds its own in direct comparisons against alpha-blockers or finasteride.

12. Further Paths

Topics, modes of action and pathways in which this substance occurs — for all those who wish to look beyond the substance.

- Interaction network

Frequently Asked Questions

Which saw palmetto extracts were investigated in the studies?

The studies employ differently prepared extracts, including a hexane extract that appears in several trials under its own preparation name (Permixon). A 2014 review describes how extraction methods alter the pharmacological profile. No uniform reference preparation exists in the literature.

What is the state of studies on benign prostatic hyperplasia?

It is broad and reaches back to the 1990s. Several meta-analyses and systematic reviews are available, together with large randomised trials, including a 2011 dose-escalation study. Heterogeneity of the extracts complicates comparison of results.

Are interactions with medicinal products known?

Interactions are a focal point of the literature. The most frequently cited works in the field are reviews on interactions of herbal products with prescription medicines; one study examined the influence on cytochrome P450 phenotypes in humans. Whether clinically relevant consequences arise from this remains an open question.

Sources

- 1 Saw palmetto extracts for treatment of benign prostatic hyperplasia: a systematic review
Wilt TJ, Ishani A, Stark G, MacDonald R, Lau J, Mulrow C · 1998
- 2 Saw palmetto for benign prostatic hyperplasia
Bent S, Kane C, Shinohara K, Neuhaus J, Hudes ES, Goldberg H et al. · 2006
- 3 Comparison of a phytotherapeutic agent (Permixon) with an alpha-blocker (Tamsulosin) in the treatment of benign prostatic hyperplasia: a 1-year randomized international study
Debruyne F, Koch G, Boyle P, Da Silva FC, Gillenwater JG, Hamdy FC et al. · 2002
- 4 Effect of increasing doses of saw palmetto extract on lower urinary tract symptoms: a randomized trial
Barry MJ, Meleth S, Lee JY, Kreder KJ, Avins AL, Nickel JC et al. · 2011
- 5 Updated meta-analysis of clinical trials of Serenoa repens extract in the treatment of symptomatic benign prostatic hyperplasia
Boyle P, Robertson C, Lowe F, Roehrborn C · 2004
- 6 Meta-analysis of clinical trials of permixon in the treatment of symptomatic benign prostatic hyperplasia
Boyle P, Robertson C, Lowe F, Roehrborn C · 2000
- 7 Randomized, double-blind, placebo-controlled trial of saw palmetto in men with lower urinary tract symptoms
Gerber GS, Kuznetsov D, Johnson BC, Burstein JD · 2001
- 8 Efficacy and safety of a hexanic extract of Serenoa repens (Permixon®) for the treatment of lower urinary tract symptoms associated with benign prostatic hyperplasia (LUTS/BPH): systematic review and meta-analysis of randomised controlled trials and observational studies
Vela-Navarrete R, Alcaraz A, Rodríguez-Antolín A, Miñana López B, Fernández-Gómez JM, Angulo JC et al. · 2018
- 9 What do we know about phytotherapy of benign prostatic hyperplasia?
Alkanjari O, Vitalone A · 2015
- 10 Serenoa repens for benign prostatic hyperplasia
Tacklind J, Macdonald R, Rutks I, Stanke JU, Wilt TJ · 2012
- 11 BPH and inflammation: pharmacological effects of Permixon on histological and molecular inflammatory markers. Results of a double blind pilot clinical assay
Vela Navarrete R, Garcia Cardoso JV, Barat A, Manzarbeitia F, López Farré A · 2003
- 12 A prospective, 1-year trial using saw palmetto versus finasteride in the treatment of category III prostatitis/chronic pelvic pain syndrome
Kaplan SA, Volpe MA, Te AE · 2004
- 13 Lack of herbal supplement characterization in published randomized controlled trials
Wolsko PM, Solondz DK, Phillips RS, Schachter SC, Eisenberg DM · 2005
- 14 Serenoa repens (saw palmetto): a systematic review of adverse events
Agabiakia TB, Pittler MH, Wider B, Ernst E · 2009
- 15 Effects of pumpkin seed oil and saw palmetto oil in Korean men with symptomatic benign prostatic hyperplasia
Hong H, Kim CS, Maeng S · 2009
- 16 Serenoa repens treatment modifies bax/bcl-2 index expression and caspase-3 activity in prostatic tissue from patients with benign prostatic hyperplasia
Vela-Navarrete R, Escibano-Burgos M, Farré AL, García-Cardoso J, Manzarbeitia F, Carrasco C · 2005
- 17 Saw palmetto (Serenoa repens) in men with lower urinary tract symptoms: effects on urodynamic parameters and voiding symptoms
Gerber GS, Zagaja GP, Bales GT, Chodak GW, Contreras BA · 1998
- 18 Saw palmetto for the treatment of men with lower urinary tract symptoms
Gerber GS · 2000
- 19 Tissue effects of saw palmetto and finasteride: use of biopsy cores for in situ quantification of prostatic androgens
Marks LS, Hess DL, Dorey FJ, Luz Macairan M, Cruz Santos PB, Tyler VE · 2001
- 20 Evaluation of male sexual function in patients with Lower Urinary Tract Symptoms (LUTS) associated with Benign Prostatic Hyperplasia (BPH) treated with a phytotherapeutic agent (Permixon), Tamsulosin or Finasteride
Zlotta AR, Teillac P, Raynaud JP, Schulman CC · 2005
- 21 Serenoa repens extract for benign prostate hyperplasia: a randomized controlled trial
Willetts KE, Clements MS, Champion S, Ehsman S, Eden JA · 2003
- 22 Evaluation of the clinical benefit of permixon and tamsulosin in severe BPH patients-PERMAL study subset analysis
Debruyne F, Boyle P, Calais Da Silva F, Gillenwater JG, Hamdy FC, Perrin P et al. · 2004
- 23 Pharmacological effects of saw palmetto extract in the lower urinary tract
Suzuki M, Ito Y, Fujino T, Abe M, Umegaki K, Onoue S et al. · 2009
- 24 Serenoa repens for benign prostatic hyperplasia
Tacklind J, MacDonald R, Rutks I, Wilt TJ · 2009
- 25 The present invention further comprises one or more of N-acetyl L-Carnitine, Ubidecarenone (coenzyme Q10), Idebenone, De...
· 2010
- 26 In some of these examples, each of the hair care products contain at least 10 vitamins, minerals, and herbs, such as swe...
· 2004
- 27 In some of those examples, each of the hair care products contain at least 10 vitamins, minerals, and herbs, such as swe...
· 2004
- 28 Patients received a fixed combination of extracts of saw palmetto fruit (Serenoa repens) and nettle root (Urtica dioica)...
· 2000
- 29 When taken for 3 months, a combination of natural products (cernitin, saw palmetto, B-sitosterol, vitamin E) compared to...
· 2001
- 30 Interactions between herbal medicines and prescribed drugs: a systematic review
Izzo AA, Ernst E · 2001
- 31 Interactions between herbal medicines and prescribed drugs: an updated systematic review
Izzo AA, Ernst E · 2009
- 32 Interactions between herbs and conventional drugs: overview of the clinical data
Izzo AA · 2012
- 33 In vivo assessment of botanical supplementation on human cytochrome P450 phenotypes: Citrus aurantium, Echinacea purpurea, milk thistle, and saw palmetto
Gurley BJ, Gardner SF, Hubbard MA, Williams DK, Gentry WB, Carrier J et al. · 2004
- 34 Unsafe and potentially safe herbal therapies
Klepser TB, Klepser ME · 1999
- 35 Selected herbals and human exercise performance
Bucci LR · 2000
- 36 Herbal interactions on absorption of drugs: Mechanisms of action and clinical risk assessment
Colalto C · 2010
- 37 Herb-drug interactions: focus on metabolic enzymes and transporters
Choi YH, Chin YW, Kim YG · 2011
- 38 Is there a scientific basis for the therapeutic effects of serenoa repens in benign prostatic hyperplasia? Mechanisms of action
Buck AC · 2004
- 39 Modern extraction techniques and their impact on the pharmacological profile of Serenoa repens extracts for the treatment of lower urinary tract symptoms
De Monte C, Carradori S, Granese A, Di Pierro GB, Leonardo C, De Nunzio C · 2014
- 40 A scientific basis for the therapeutic effects of Pygeum africanum and Serenoa repens
Levin RM, Das AK · 2000

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