

“Rotten cheese steep’d in tobacco”:

The history of saw palmetto (*Serenoa repens*) from crop and foodstuff to a recognised medicinal plant

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Note on previous publication:

English update of the German article: “Die Sägepalme — Von Nutzpflanze und Nahrungsmittel zur anerkannten Arzneipflanze,” Zeitschrift für Phytotherapie 2017; 38(05):235–239. DOI: [10.1055/s-0043-115589](https://doi.org/10.1055/s-0043-115589).

Abstract

Background: *Serenoa repens* (saw palmetto) is a Floridacentred palm whose fruits transitioned from food/fibre to pharmacy. Indigenous uses are diverse but largely nonmedicinal; medical adoption accelerated in the late 19th/early 20th century and was later standardised via USP/NF. Modern EU regulation distinguishes extract types.

Aim: To document the trajectory from utilitarian plant to medicinal product; to trace commercialisation and pharmacopoeial status; to appraise current evidence and regulation (HMPC/EAU).

Sources and methods: Critical reading of primary/secondary sources in ethnobotany and pharmacy history (18th–20th c.); USP/NF; eclectic/homoeopathic literature; EMA/HMPC monographs; evidence syntheses (Cochrane 2023; metaanalysis 2024) and clinical reviews; EAU guideline 2024.

Results: Historically, preparations and indications proliferated; fruits were listed in USP (1906–1916) and NF (1926–1950). Today, product quality is specified in Ph. Eur.; hexane extracts (HESr) show small, extractdependent benefits for LUTS/BPH with good tolerability; ethanolic/aqueous preparations show heterogeneous findings. HMPC classifies HESr as well-established use; ethanolic/aqueous as traditional use. EAU 2024: offer HESr when tolerability is prioritised, informing about modest effect size.

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Update since 2017: New evidence syntheses (Cochrane 2023; WJMH 2024) and an EAU 2024 update; HMPC status unchanged.

Conclusion: Saw palmetto illustrates the path from regional resource to regulated phytotherapy. Clinically, HESr remains an option for symptomatic BPH when minimising adverse effects is important; extract type is decisive.

Keywords: *Serenoa repens*; saw palmetto; ethnobotany; USP; NF; HMPC; HESr; BPH; LUTS; EAU guideline; pharmacopoeia; traditional use; hexane extract; safety

Botany

Saw palmetto (*Serenoa repens* (W. Bartram) Small; Arecaceae) is native to the southeastern United States and is found primarily in the state of Florida, where after the Second World War it still covered about 10 % of the land area, and it also occurs in parts of Georgia, South Carolina, Alabama, and Mississippi. [13, 45]

The botanical name is attributed to J. D. Hooker and is said to commemorate Sereno Watson, a botanist at Harvard University. [49]

The epithet “repens” is derived from the creeping appearance of the plant’s stems. [49] This bisexual fan palm is multi-stemmed, shrub-like, and can reach heights of 1–3 m. The petioles are strongly serrate, and the flowers are creamcoloured and fragrant. [49] The drupes are the plant part used medicinally today; their oil content can reach up to about 13 %. [40]

Historically relevant synonyms include *Sabal serrulata* and *Serenoa serrulata*; “*Sabal*” is still a name commonly used in pharmacy for the drug or the whole plant. Rarer synonyms include *Corypha repens* W. Bartram, *Brahea serrulata* (Michaux) H. Wendland, *Chamaerops serrulata* Michaux, *Corypha obliqua* W. Bartram, and *Diglosophyllum serrulatum* (Michaux) Wendl. ex Drude. [49, 1]

Contrary to various statements in the literature, saw palmetto was not and is not native to Egypt, nor was it already used there for medicinal purposes in antiquity. [11] Rather, this seems to go back to a misunderstanding—subsequently taken over without verification—of the claim that plant-based medicines were already used in Egypt around 1500 BCE for urological complaints. [11]

In any case, in various sources from 1998 that are supposed to document a use of saw palmetto in Egypt, nothing of the sort can in fact be found. [34]

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Traditional use

Saw palmetto is one of Florida's most versatile useful plants. It was and is used as a food source, for obtaining fibre, oil, and wax, for thatched roofs, and for medicinal purposes. [13] The Native American Ethnobotany Database lists a total of 12 sources for traditional uses among the Choctaw and above all among the Seminole. [35] The Choctaw living in what are now the states of Mississippi, Alabama, and Louisiana used the fibres to make baskets, as is likewise reported for the Coushatta and Mikasuki. [7, 42] The Seminole, who at that time settled in northern Florida, used saw palmetto in a more diverse fashion: in addition to using fibres for baskets, brooms, and ropes, they also used the fruits as food and as a market product; they furthermore used parts of the plant for ceremonies (dance fans and rattles), for tools and toys (dolls), and for fishing. [42, 35]

A specifically medicinal use is not found in the Native American Ethnobotany Database and, more generally, saw palmetto as a medicinal plant is difficult to substantiate among Indigenous peoples and European settlers up into the nineteenth century. [35, 11, 3] Other palm species such as *Sabal yapa* or the dwarf palmetto (*Sabal minor*) are better documented—for example among the Maya or the Houma. [1, 43] European settlers in North Carolina used the leaves of a small palm (“dwarfish kind”) as brooms—and nothing more—as reported by John Brickell in 1737. [5] Benjamin Hawkins reported in 1798/99 that the berries of a “dwarf saw palmetto” served as food for bears, deer, turkeys, and the Muskogee. [21] In neither case can it be proven beyond doubt that the plant was *Serenoa repens*; *Sabal minor*, still commonly known as “dwarf palmetto,” would also be conceivable. [11] An unspecified palm fruit is also said to have been a staple food of the Ais; the fruit, however, was inedible for Whites. Thus, Jonathan Dickinson already reported in 1700 on the taste: “... nothing else, but rotten Cheese steep'd in Tobacco.” [12]

Francis Peyre Porcher described in 1849 a purgative effect of the pulp: “The pulp is very sweet, but is possessed of a purgative property, often producing a copious evacuation, attended [sic] with griping.” [37] This may be a case of confusion with Spanish bayonet (*Yucca gloriosa*), whose purgative effect is also mentioned by William Bartram. [2]

Late 19th and early 20th century

Among the numerous indications listed in the literature of the 19th and early 20th centuries for the fruits of saw palmetto were, among others, alcoholism, asthma, abdominal pain, bronchitis, diabetes, diarrhoea, colds, obesity, gonorrhoea, hair loss, haemorrhoids, impotence, headaches, and kidney disease. Saw palmetto was also used in tumours, as a sedative and aphrodisiac, to improve semen production and regulate hormones, in atrophies of the testes and the breast, generally for breast enlargement, against rheumatism, and in enlargement of the prostate. [20, 10, 38, 26]

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In 1879, J. B. Read named above all those cases in which a very nourishing remedy would be appropriate. Through soothing effects on the mucous membranes, sleep would be induced, the most troublesome cough eased, expectoration facilitated, and digestion likewise promoted; moreover, fat, flesh, and strength would increase. The sedative and diuretic properties were remarkable. He further listed as indications cardiac asthma, tuberculosis (especially of the larynx), chronic bronchitis, and dilatation of the bronchi. In catarrhs, saw palmetto was said to act quickly and durably. Read concluded with the following anecdote, which since then has been reproduced in numerous variations and sometimes verbatim (for example by Hale 1898, p. 8): “The animals of Florida, emaciated as a result of the summer heat and the resultant shortage of food, put on so much fat after eating the ripe, oil-rich fruits that they soon become easy prey for hunters.” [38]

Already a year earlier, Abraham A. Solomons, likewise from Savannah, Georgia, had applied for a U.S. patent for a preparation of saw-palmetto fruits with milk sugar; as an indication, however, he cited only “various forms of disease.” [20]

In a still readable treatise of 1898, Edwin M. Hale summarised in over 100 pages all the aspects of saw palmetto then known, beginning with “overzealous” botanists who repeatedly changed the plant’s name (p. 4) and with passages taken—in part verbatim and in the first person—from Read (pp. 7 f.). As essential constituents, oils, tannins, and resins were assumed at the time; a syrup without the oil contained an alkaloid, resin, and glucose (p. 17). [20]

For a tincture, Hale gave the following instructions: fresh, ripe berries and seeds should be crushed and macerated for 14 days in alcohol (90 % v/v); the tincture should then be decanted but not filtered through paper or cloth, since otherwise the oil would be filtered out as well. He described a fluid extract as four times stronger, but one should not prepare a tincture from it; the fluid extract could, however, be combined with syrup. He also listed as dosage forms oil, saccharated oil, “Malto-Sabal” (with malt extract), aqua oleum sabal, and anal and vaginal suppositories with 5–10 drops of the oil in cocoa butter, to be used, among other things, for haemorrhoids and gonorrhoea. [20]

Hale described or quoted in detail several homoeopathic provings that were subsequently taken up many times. Thus, in a young woman, prolonged intake of a *Sabal* tincture over the winter months was said to have enlarged the breasts by one third. [20]

John Uri Lloyd pointed out in 1905 the paradox that effects such as the enlargement of “wasted” (his term) breasts, ovaries, and testes were named, while saw palmetto was at the same time recommended for an enlarged prostate. He described the fruits as nutritive as well as strengthening and listed effects as an expectorant and in inflammation of mucous membranes. In addition, saw palmetto could be useful in various forms of cough, laryngitis, catarrh, asthma, and in different manifestations of tuberculosis. [26]

United States Pharmacopoeia and National Formulary

From 1906 to 1916, the ripe, partially dried fruits were listed in the 8th revision of the United States Pharmacopoeia (p. 383), and from 1926 to 1950 in the National Formulary. Shortly before the First World War, saw palmetto was official only in the USA. Wilhelm Mitlacher wrote in 1912 of the berries: “They are said to act as diuretics and as a sexual stimulant. In Europe they are not in use.” At the same time, Alice Henkel in the USA described use as a digestif and to relieve inflammation of the mucous membranes; she gave the harvest period for the berries as August to January, with ripening from October to December. [26, 22, 33]

On the German market since 1938

In his 1938 textbook, Gerhard Madaus drew first and foremost on John Henry Clarke’s 1902 work, which in turn relied on Hale 1898 and other already cited authors such as Read. On the basis of his own research, Madaus listed—besides prostatic hypertrophy—the “decongestion of the prostate,” bladder disorders accompanying prostatic hypertrophy such as cystitis (including acute cystitis with bladder-neck irritation in men and women), dysuria (“very useful”) and enuresis, as well as orchitis, epididymitis, and chronic gonorrhoea. Finally, he named bronchitis, stubborn cough, tumours, fluor albus, too-small breasts, and eczema. [30, 10]

In 1940, Christensen and Stokes likewise pointed out contradictions in the literature. They first described in detail the harvesting and drying of the fruits for commercial use and then devoted extensive attention to the previously only poorly documented histology of fruit and seed, including microscopic examination of the powdered drug. [9]

A combination drop preparation containing saw palmetto, aspen, nettle herb, and cantharidin (“Spanish fly” = *Lytta vesicatoria*) had been on the German market since 1938; from 1969 onward there were also capsules with saw palmetto, nettle, and poplar. According to Fintelmann et al., combinations appear sensible and long-term use is considered unobjectionable. The Commission E monograph “*Sabal fructus* (saw-palmetto fruits)” of 1989/1991 lists as indications micturition complaints in benign prostatic hyperplasia, stages I to II. [16]

Modern use

Today, the quality of saw-palmetto fruits (*Sabal serrulatae fructus*) and of saw-palmetto extract is specified by the European Pharmacopoeia (Ph. Eur.). The fruits consist of peel (36 %), pulp (16 %), seed coat (10 %), and seed (38 %), and they contain, as constituents considered relevant for efficacy, saturated fatty acids, fatty acid ethyl esters, fatty alcohols, lauric, oleic, myristic, palmitic, linoleic and linolenic acid, phytosterols, as well as gibberellic acid and water-

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soluble polysaccharides. [4] According to the Ph. Eur., *Sabalís serrulatae fructus* must contain at least 11 % total fatty acids. For *Sabalís serrulatae extractum*, the Ph. Eur. defines identity/assay via the fatty-acid profile, including a minimum content of lauric acid. By contrast, the USP monographs for saw palmetto extract specify not less than 80 % total fatty acids and not less than 0.2 % total sterols.

Clinically confirmed effects include the antiandrogenic action of the hexane extract and the anti-exudative effect of the aqueous extract. Experimental studies point to anti-oedematous, antiinflammatory, antiproliferative, and anticongestive actions. [4] The antiinflammatory effect of a hexane extract has also already been observed clinically. [27] In addition, research is being conducted into its use in prostate carcinoma and into topical applications in androgenetic alopecia and acne; oral intake in polycystic ovary syndrome (PCOS) is at least conceivable. [39, 17, 48, 31, 36]

The Cochrane update concludes that saw palmetto alone provides little to no benefit for LUTS due to prostatic enlargement, whereas analyses focused on hexane extracts (HESr) report signal-level benefits (e.g., Qmax, nocturia) and, in some trials, outcomes comparable to α -blockers—highlighting that the extract type matters. [18, 19, 4]

HMPC: the extraction solvent matters

The Committee on Herbal Medicinal Products (HMPC) of the European Medicines Agency (EMA) has recognised the use of saw-palmetto fruits in the form of soft extracts (DER 7–11:1, extraction solvent hexane) for the symptomatic treatment of benign prostatic hyperplasia (BPH), while ethanolic extracts and aqueous preparations have been classified as traditional herbal medicinal products (under § 39a AMG). Based on long-standing experience, these can be used to relieve symptoms of BPH when a serious disease has been excluded by a physician. [23] In the current monograph, hexane-extracted *Serenoa repens* is classified as well-established use for symptomatic BPH, whereas ethanol extracts remain traditional use. [23]

BPS guideline

In the S2e guideline on the treatment of benign prostatic syndrome (BPS), saw-palmetto fruits are counted among the “most frequently used and best-studied phytotherapeutics” for the treatment of BPH; at the same time, the heterogeneity of extraction procedures (e.g., hexane vs. ethanol) is emphasised as a factor that can lead to contradictory study results. [24, 14] Since placebo-controlled studies are now available, anecdotal case reports play hardly any role in safety assessment. [4] As a rule, the preparations are better tolerated than the medicinal alternatives from the classes of the α 1-adrenoceptor antagonists (e.g., tamsulosin) and the 5 α -reductase inhibitors

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(e.g., finasteride). [4] In one study, there were even fewer adverse effects in the verum group than in the placebo group. [8] In addition to monopreparations, combinations exist—for example with nettle-root extract. [28, 29]

The 2024 EAU guideline distinguishes between extracts: hexane-extracted *Serenoa repens* shows improvements in Qmax and nocturia vs. placebo and has minimal sexual adverse effects; recommendation: offer HESr to men wishing to avoid adverse effects, while informing them that the magnitude of benefit is modest (strength: Weak for offering; Strong to inform). [14]

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Document metadata

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Version: 1.1 (22 Oct 2025)

Status: Public release

Suggested citation: Niedenthal T. "Rotten cheese steep'd in tobacco": The history of saw palmetto (*Serenoa repens*) from crop and foodstuff to a recognised medicinal plant. Version 1.0; 19 Oct 2025. DOI: [10.5281/zenodo.17389152](https://doi.org/10.5281/zenodo.17389152).

Funding: none

Competing interests: none

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Zenodo metadata (EN/DE)

EN title: "Rotten cheese steep'd in tobacco": The history of saw palmetto (*Serenoa repens*) from crop and foodstuff to a recognised medicinal plant

EN abstract: *Serenoa repens* (saw palmetto) moved from a versatile Florida crop and foodstuff to a medicinal plant with recognised use in symptomatic BPH. Indigenous uses are diverse but not clearly medicinal. Industrial production and eclectic/homoeopathic traditions shaped 19th/20th century practice; modern evidence emphasises extract specificity (hexane vs ethanol) and safety. Regulatory status in the EU recognises hexane extracts (well-established use) while ethanolic/aqueous preparations are traditional herbal medicinal products.

EN keywords: *Serenoa repens*; saw palmetto; ethnobotany; BPH; HMPC; hexane extract; pharmacopoeia; EAU guideline; LUTS; safety

DE Kurzabstract: *Serenoa repens* (Sägepalme) wurde in Florida als Nutz und Nahrungspflanze vielfältig genutzt; eindeutig medizinische Anwendungen sind in den indigenen Quellen schwer zu belegen. Im 19./frühen 20. Jh. setzte eine breite medizinische Verwendung ein (inkl. homöopathischer Traditionen). Heute sind HexanExtrakte für die symptomatische BPH anerkannt, während ethanolsche/wässrige Zubereitungen als traditionelle pflanzliche Arzneimittel gelten; Studienlage und Leitlinien betonen die Bedeutung des Extrakttyps.

Related identifiers: DOI [10.5281/zenodo.17389152](https://doi.org/10.5281/zenodo.17389152); older German version: DOI [10.1055/s-0043-115589](https://doi.org/10.1055/s-0043-115589)

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