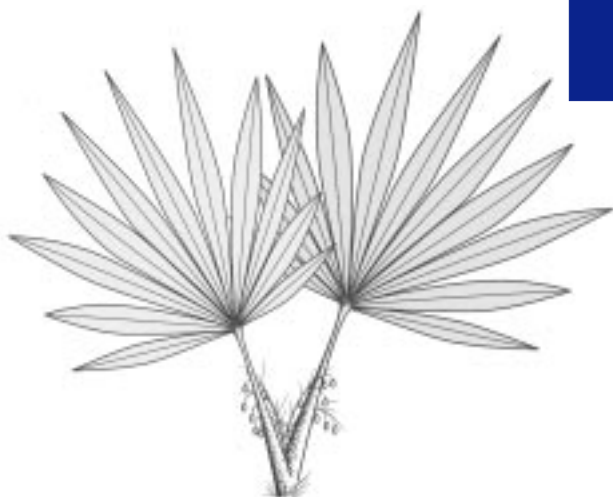


# Monograph



## Serenoa repens

**Common Name: Saw Palmetto**

### Description and Constituents

*Serenoa repens* (also known as *Sabal serrulata*, Saw Palmetto or Dwarf palm) is native to the United States South Atlantic coast and Florida, as well as Southern Europe and North Africa. This small palm tree grows to a height of six to ten feet, and has a fan-shaped crown of leaves and dark red berries approximately the size of olives.

Traditional indications for the use of Saw palmetto include: cystitis, chronic bronchitis, asthma, diabetes, dysentery, indigestion, and for “underdeveloped breasts.” The berries have also been thought to be an aphrodisiac.<sup>1</sup> Modern usage of Saw palmetto is overwhelmingly for the treatment of benign prostatic hyperplasia (BPH).

The berries contain approximately 1.5 percent volatile oil, of which 63 percent are free fatty acids and 38 percent are ethyl esters of those fatty acids. The fatty acids include: caproic, caprylic, capric, lauric, palmitic, and oleic acids, and ethyl esters of these. In addition, the berries contain beta-sitosterol and its glucoside, beta sitosterol D-glucoside, as well as ferulic acid.<sup>1</sup>

### Clinical Uses and Mechanisms of Action

The liposterolic extract of the fruit, standardized to contain at least 85 percent fatty acids and sterols, is currently used in the treatment of BPH.

Benign prostatic hyperplasia is one of the most common medical conditions in middle-aged and elderly males, with an incidence of approximately 50-60 percent in men age 40-60, and greater than 90 percent in men over 80. The disease process leading to symptomatology in older males probably begins as early as the late 20s, and may have an incidence rate of 10 percent at that age. Rarely a fatal disease, BPH affects the patients’ lifestyle and comfort.<sup>2</sup>

A non-malignant hypertrophy of the prostate which is caused by hormonal processes and/or imbalances within the prostate, BPH begins in the periurethral region and includes the stromal, epithelial, and smooth muscle tissues of the gland. The fibrous capsule surrounding the gland forces most of the growth inward, compressing the urethra and causing the typical urinary symptoms characteristic of the disease, including: decreased force and caliber of the urine stream, urinary hesitancy, urgency, frequency, post-void dribbling, incomplete emptying of the bladder, dysuria, and nocturia.<sup>2</sup>

Testosterone is converted in prostatic cells to dihydrotestosterone (DHT), catalyzed by the enzyme steroid 5-alpha-reductase (5-AR). DHT binds to androgen receptors in the nucleus of prostate cells, stimulating cellular growth and division.<sup>3-5</sup> In BPH tissue, 5-AR levels are higher than in tissue not

affected by BPH.<sup>4,5</sup> The presence of DHT may also stimulate 5-AR activity, causing a positive feedback loop, and more DHT.<sup>6</sup> The standardized liposterolic Serenoa extract has been found to be a potent inhibitor of 5-AR, resulting in decreased tissue DHT. Serenoa also competitively inhibits binding of testosterone and DHT to cytosolic and nuclear androgen receptors.<sup>7-9</sup>

Another component of BPH is inflammation within the prostate gland. A standardized Serenoa extract has been shown to inhibit 5-lipoxygenase and thus the downstream pro-inflammatory arachidonic acid metabolites leukotriene B4 (LTB4) and 5-hydroxyeicosatetraenoic acid (5-HETE).<sup>10</sup>

### **Clinical Studies**

In a double-blind, placebo-controlled study of 110 BPH patients, 160 mg twice per day of a standardized Serenoa extract significantly improved nocturia, dysuria, post-voiding residual urine, flow rate, patient self-rating, and the physician's overall assessment.<sup>11</sup> In another double-blind clinical study, urinary symptoms and flow rates were significantly improved in 42.9 percent of patients taking a Serenoa extract, versus 15.4 percent of patients given placebo.<sup>12</sup> In an open trial, 67 percent of patients on Serenoa described their subjective symptom relief as "excellent", while 25 percent characterized their relief as "good".<sup>13</sup> No side effects or toxicity were noted.

The standard pharmaceutical therapy for BPH is the drug Proscar® (finasteride), a 5-AR inhibitor. A six-month, double-blind study of 1,098 BPH patients over 50 years of age compared Proscar (5 mg per day) with a standardized Serenoa extract (160 mg twice per day). Both treatments decreased BPH symptoms equally, and improved quality of life. Even though both treatments significantly improved symptomatology, it is interesting to note that Proscar reduced prostate size by 18 percent and the Serenoa extract reduced it six percent.<sup>14</sup>

### **Dosage**

The dose of the standardized liposterolic Serenoa extract (85 - 95% fatty acids and sterols) used in the majority of clinical studies on BPH is 160 mg twice per day. Clinical results may be seen in six to eight weeks, although a six-month trial is the minimum to assess clinical efficacy.

### **Toxicology**

There are no known cases of toxicity. Occasionally, patients experience minor gastrointestinal symptoms (nausea, abdominal pain).<sup>15</sup>

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