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File: ■ Saw Palmetto (*Serenoa repens*)
■ Adverse Events
■ Safety

HC 090595-393

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RE: A Review of Adverse Events in the Use of Saw Palmetto: Safety Confirmed

Agbabiaka TB, Pittler MH, Wider B, Ernst E. *Serenoa repens* (saw palmetto). A systematic review of adverse events. *Drug Saf.* August 8, 2009;32(8):637-647.

Saw palmetto (*Serenoa repens*) is a shrub or small tree in the palm family native to the southeastern United States. Today, extracts of dried saw palmetto berries are used to treat lower urinary tract infections and benign prostatic hyperplasia. Given the widespread use of saw palmetto, it is important to investigate its safety. The purpose of this review article is to describe the available human safety data on saw palmetto.

The literature review was conducted by researchers at the Universities of Exeter and Plymouth in Exeter, United Kingdom and the Institute for Quality and Efficiency in Health Care in Cologne, Germany. The researchers searched the databases of MEDLINE, AMED, EMBASE, CINAHL, and the Cochrane Library, and hand-searched the reference lists of all relevant articles. The researchers also requested information from adverse event reporting systems in Australia, Germany, the United States, and the United Kingdom; the World Health Organization; manufacturers of saw palmetto products; and herbal organizations in the UK. The review included all reports of human use of saw palmetto monopreparations. There were no language restrictions, but data from animals, in vitro models, and human use of combination products were not included in the review.

The search identified 140 articles, of which 40 met the criteria for evaluation. These included 26 randomized controlled trials, 4 non-randomized controlled trials, 6 uncontrolled trials, and 4 case reports. The study population was primarily men diagnosed with benign prostatic hyperplasia, prostate cancer, or lower urinary tract infection, although two studies included women. Saw palmetto extract was administered orally in daily doses ranging from 100 mg to 480 mg for durations ranging from less than six months to more than two years. The World Health Organization and national adverse event reporting systems received 389 adverse event reports related to saw palmetto monopreparations. Only three of the 24 manufacturers responded and provided safety information, and none of the four herbal organizations provided information.

The majority of adverse effects reported were mild, infrequent, and reversible. The most frequently occurring adverse events were abdominal pain, diarrhea, nausea, fatigue, headache, decreased libido, and rhinitis. No drug interactions were reported for saw palmetto.

The authors conclude that saw palmetto is well tolerated and is not associated with serious adverse events. The authors explain that the systematic evaluation of adverse events related to herbal therapy is difficult. Data must be combined from very different types of reports. There is no standard methodology to evaluate the findings, the quality of the reporting is uneven, and pooling of data for statistical analysis is not feasible. However, the combination of experimental studies and observational data can be used to generate evidence needed to critically evaluate the safety of an herbal therapy.

–Heather S. Oliff, PhD

The American Botanical Council has chosen not to reprint the original article.

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