



COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

SERENOA REPENS

SUMMARY REPORT

1. *Serenoa repens* (synonym: saw palm) is a plant of the family *Arecaceae* (*Palmae*). *Serenoa repens* is a bushy palm with deep-red, nearly black, berry-like fruits (sabal fruits). *Serenoa repens* is distributed in the southern states of North America, predominantly South Carolina and Florida, and in the tropic regions of Middle and South America. The homeopathic mother tincture is prepared according to homeopathic pharmacopoeias by ethanolic extraction of the fresh fruits of *Serenoa repens*.

The fruits of *Serenoa repens* contain carbon hydrates, acidic polysaccharides, and sterols. The main sterol is β -sitosterol and its derivatives. Further constituents are flavonoids (quercitrin, kaempferol, uronic acid), fatty acids, essential oils and anthranilic acid.

2. In veterinary homeopathy the mother tincture is intended for oral or parenteral use in all food-producing species. The use follows the principles of homeopathic therapy where animals are diagnosed on basis of the individual pattern of clinical signs. The recommended maximum parenteral dose for large animals is 10 ml/animal. Corresponding doses in form of tablets, globules or drops are reported to contain lower amounts of *Serenoa repens* than the injectable form. Treatment may be repeated but a fixed dose schedule is not common in homeopathy.

Serenoa repens (sabal extracts) is also used in human phytotherapy for treatment of prostatic hypertrophy. Adverse effects are rare; they include mild symptoms of gastrointestinal disorders. The recommended daily dose of the drug (dried berries) is reported as 1 to 2 g or 320 ml of a hexane extract.

3. Oily and water-soluble extracts of the fruits of *Serenoa repens* exert anti-inflammatory activity on acute oedema in rats and mice. An intravenous dose of 0.1 to 1 mg/kg bw of an acidic polysaccharide extract obtained from the fruits reduced carrageenan-induced paw oedema in rats by 50%. Despite the anti-inflammatory effects the acidic polysaccharides are reported to have a stimulating effect on the immune system, in particular on the activity of phagocytes. The relatively high amount of sitosterol contained in extracts of the fruits may exert estrogenic effects. Subcutaneous administration of 2.5 and 5 mg/animal of a methanolic extract obtained from the dried fruits of *Serenoa repens* to female mice increased the uterus weight by approximately 30% in comparison to the control group. An anti-androgenic effect of hexane extracts of dried fruits in male mice has been described. Castrated male mice treated with testosterone (3 μ g/animal per day for 12 days) and a sambal extract (300 mg) showed a neutralisation of the testosterone-induced increases of prostate weights. The anti-androgenic effect of β -sitosterol is attributed to an inhibition of the enzyme 5- α -reductase which metabolises testosterone to dihydrotestosterone, and the substance is reported to act as an antagonist on some types of dihydrotestosterone receptors, especially in the prostate.
4. Information on the pharmacokinetics and metabolism of *Serenoa repens* or its preparations was not provided.

5. For the hexane extract of the dried fruits from *Serenoa repens* an oral LD₅₀ value of 54 ml/kg bw has been reported for male rats.
6. No specific information on repeated dose toxicity, mutagenicity, teratogenicity and carcinogenicity of *Serenoa repens* was provided.
7. In a preliminary risk evaluation procedure by the Committee for Veterinary Medicinal Products considering all defended old substances used in veterinary homeopathy in concentrations greater than 1:10 000, the use of *Serenoa repens* and its individual constituents was considered as not giving rise to specific health concern. Further information made available and extensive search of published literature did not provide any further evidence for pharmacological or toxicological properties of *Serenoa repens* and its constituents alerting to specific health risks which may result from residues in food producing animals following the intended uses. Special emphasis was put on identification of any suspicion pointing to genotoxicity or other potential of serious health effects of plant constituents. Phytosterols such as those present in *Serenoa repens* are common natural constituents of many plants, which are used as human or animal foodstuffs. Any residues of phytosterols in meat or milk of animals treated with *Serenoa repens* can be considered negligible compared to the normal level of phytosterol intake of animals and humans via food.

Conclusions and recommendation

Having considered the criteria laid down by the Committee for Veterinary Medicinal Products for the inclusion of substances in Annex II of Council Regulation (EEC) No 2377/90 and in particular that:

- *Serenoa repens* is used only in a small number of individual animals for non-regular treatments,
- the animals are unlikely to be sent for slaughter during or immediately after treatment,
- *Serenoa repens* and constituents thereof do not give rise to specific consumer health concern which may result from veterinary homeopathic uses in food producing animals;

the Committee for Veterinary Medicinal Products concludes that there is no need to establish an MRL for any constituents of *Serenoa repens* and recommends its inclusion in Annex II of Council Regulation (EEC) No 2377/90 in accordance with the following table:

Pharmacologically active substance(s)	Animal species	Other provisions
<i>Serenoa repens</i>	All food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias at concentrations corresponding to the mother tincture and dilutions thereof only